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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,585	03/04/2002	Esa-Matti Lilius	2328-124	6319

6449            7590            05/04/2004

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[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1645

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/980,585	LILIUS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 February 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) 1 and 3-10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

**FINAL ACTION**

1. Applicants' amendment and response filed February 6, 2004 is acknowledged. Claim 1 and paragraphs [0012-0013] have been amended.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior office action.

***Claim Rejections Withdrawn***

3. Rejections under 35 U.S.C. 112, 1<sup>st</sup> paragraph of Claims 1-10, paragraph 3, pages 2-3 of the previous Office Action.
4. Rejections under 35 U.S.C. 112, 2<sup>nd</sup> paragraph of Claims 1-10, at paragraph 4, pages 3-4 of the previous Office Action.
5. Rejection under 35 U.S.C. 103(a) of Claims 1-10, at paragraph 6, pages 6-8 of the previous Office Action.

***REJECTIONS MAINTAINED***

6. The rejection of amended Claims 1, 2-4, and 6-7 are hereby maintained under 35 U.S.C. 102(e) as being anticipated by Szalay *et al.* in US Patent 5,976,796 published 2 November 1999 for the reasons set forth on page 5, paragraph 2;

The rejection was on the grounds that:

GFP and luciferase activities were measured following a 12 hr incubation period using inverted fluorescent microscope for GFP activity and luminometer for luciferase activity at column 5, line 62 – column 6, line 11. Since measurements were indicative of either luciferase or fluorescence of actively growing cells in culture, the cells measured were either alive at any moment, are or have been alive when tested.

Applicants urge that Examiner is in error in this rejection based on the grounds Szalay *et al.*:

- a. Only disclose the measurement of gene expression in live cells,
- b. Does not disclose or suggest the assessment required by step (c) of claim 1,
- c. Does not disclose or suggest that by using (at least) two markers, each correlating with a different member of the group - - the cells that have lived, the cells that are alive and the cells that have died – one can assess the growth rate and death rate of the microorganism.

Applicants' arguments filed February 6, 2004 have been fully considered but they are not found persuasive. It is the Examiner's position that Applicants' Claim language set forth in 1(c) does not absolutely require that death rate has to be assessed, only that growth and death rate of the microorganism is assessed based on at least two (emphasis added) of the following: i), ii) or iii) and further, there is no stipulation regarding a chosen time period in known proportions.

***New Grounds of Objections/Rejections Necessitated by Amendment***

***Claim Objections***

7. Amended Claim 1, and Claims 3-10 are objected to because of the following informalities:

- (a) Claim 1 – Replacing “...of interest by” with “...of interest comprising” will clarify claim language.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject matter. The claims are indefinite in the recitation of “which method is characterized in that” (Claim 1) and “characterized in that” (Claims 3-10) because it is unclear from the specification what applicant intends. Clarification is required in order to overcome this rejection. The examiner respectfully suggests that the claims be amended to recite “wherein” instead of “...which method is characterized in that” and “characterized in that”.

Claims also are unclear because they appear to lack positive active method steps. The examiner further suggests that the claims be amended as follows:

- (b) Claim 1, b), delete “said” replacing with “incubating” and delete “is incubated”.
- (c) Claim 1, c), insert “assessing” before “the growth...” and delete “is assessed”.

9. Claims 5, 8-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Status of the Claims***

10. No claims are allowed.

***Conclusion***

11. Applicants' amendment necessitated the new grounds of objection/rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL.** (See MPEP § 706.07(a)). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS for the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856.

The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Tammy K. Field*  
Tammy K. Field

May 3, 2004

*NITA MCKEEFIELD*  
NITA MCKEEFIELD  
PRIMARY EXAMINER  
*5/3/04*